

43. (Amended) The endoscopic [instrument] system of claim 40, wherein said light source emits pulsed light at least in a spectral excitation range of the fluorescing substance, and a pulse frequency corresponds to a video image frequency of said endoscopic camera.

44. (Amended) The endoscopic [instrument] system of claim 42, wherein said observation instrument has, at a distal end thereof, a transparent element having a fluorescing substance.

REMARKS

Regarding priority, the present application is a continuation of PCT/EP 98/04575 pursuant to 35 U.S.C. §§ 120 and 363. The present application does not claim § 119 priority from the PCT application. As such, the claim for priority to DE 197 31 894.0 can be traced back through the PCT application, as the PCT application claims priority therefrom.

With respect to the Information Disclosure Statement, Applicant notes that DE 195 29 950 and DE 39 33 159 are foreign counterparts to U.S. Patent Nos. 5,820,545 and 4,945,894 respectively. Copies of these U.S. Patents were submitted along with

the Information Disclosure Statement. The Examiner should readily be able to determine the relevance of these references from the English language equivalents. With respect to DE 197 31 894, this document should not have been listed on the IDS, as it is not prior art to the present application. Rather, this is the German priority document from which the present application claims ultimate priority. Note line 30 on the face of the PCT application from which the present application claims continuation status.

Claims 1-43 are objected to because of an informality in the preamble. All Claims have been amended to correct this informality.

Claims 20, 22, 42 and 44 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 20 and 42 have been amended to obviate this rejection.

All claims stand rejected under 35 U.S.C. §103(a) as being unpatentable over Iacovelli (U.S. Patent No. 5,350,391) in view of Gain (U.S. Patent No. 3,840,015) and in some cases further in view of various tertiary references. This rejection is respectfully traversed.

As stated in the specification starting from para. 2 on page 2, up to page 4, the invention concerns particular kinds of surgeries. The generic terms for these kinds of surgeries are "photodynamic diagnosis" (PDD) and "photodynamic therapy" (PDT). These specific surgeries are based on the phenomena that some kinds of tissue, in particular cancer tissue, show fluorescence when illuminated with a specific light (called "excitation light").

A great problem with known systems is that the fluorescence phenomena shown by the tissue occurs with a very low intensity. The surgeon who observes the operation site within the body has a view which is similar to that of looking into a darkened room showing some light with very low intensity. A second problem associated with known systems is that the usually used instruments which are made of steel can not be seen since the excitation light is not reflected in the visible range and steel does not show a fluorescence phenomena. In other words, the surgeon can not see the medical instrument.

Therefore, according to the current state of the art, it is necessary that the surgeon switches on a light source, usually a "white" light lamp, to see the position of the medical instrument. However, this "white" light is of high intensity and, after switching off this "white" light for returning to the fluorescence modus, the eye of the surgeon needs several seconds to adapt to the low intensity fluorescence light.

The problem with this can be illustrated by an example. If you are in a room which is well-illuminated and you switch off the light, you see nothing or only black. Your eyes will need some seconds to accommodate to this situation and after 10 or 20 seconds, you will be able to see at least some contours in this dark room. If now, you turn on the light again and the room is illuminated, you will immediately see everything. If you turn off the light again, your eye will need a certain accommodation period to become accustomed to the dark. If you continue with this procedure 5 or 10 times, your eyes will become confused and the accommodation phase will become longer and longer, which is very disagreeable for the person. This is the situation the surgeon is faced with when performing PDD or PDT surgery with known systems. He or she has to switch several times from the low-intensity fluorescence modus (during which he or she can see the tissue to be treated) to the high light intensity white light (when he or she can observe the instrument).

The present invention is concerned with remedying this problem. As such, all claims require that the instrument be marked with a fluorescing substance selected in the excitation range of either a tumor-specific photosensitizer (Claim 1) or a tissue-autofluorescence (Claim 23).

As explained in the introductory part of the application, there are some chemical compounds like ALA which enhance the fluorescence phenomena of a tissue since this chemical compound is accumulated in special areas of the tissue, in particular in cancer tissue. With such a chemical compound, it is possible to make the natural autofluorescence of that tissue more intensive. With the present invention, it is now possible to make both the tissue and the instrument visible with one light source.

It is not necessary to switch between two different lamps during the surgery and therefore, there is no necessity for the surgeon to adapt his or her eye to different lights of different intensities.

The cited references do not disclose, teach or suggest these limitations.

Iacovelli fails to disclose performing a surgery in the fluorescence modus, i.e. to bring the tissue to fluorescence by irradiating it with a specific excitation light. Iacovelli teaches to make colored stripes on the surface of blades to give a surgeon the impression of a three-dimensional view of the operation site which he or she only sees as a two-dimensional picture on a video-monitor. If one reads the passage cited by the Examiner on column 7 starting at line 15, one can see that the colored stripes at the blades assist the surgeon in controlling how deep the cut is made with the blade.

Iacovelli teaches to provide colors which are remarkably different from the colors of the tissue. The colors disclosed by Iacovelli are colors which can be seen in the visible light, and therefore, the teaching thereof is to irradiate the tissue with visible light of high intensity. Under these circumstances, it is impossible to perform a surgery using the fluorescence phenomena of the tissue, since with visible white light, one cannot observe this fluorescence phenomena of the tissue. In other words, with the teaching of Iacovelli, it is impossible to perform a surgery as disclosed in the present application.

The indication on column 7, line 30, of Iacovelli to improve the visibility by using a photoluminescent coating teaches only to enhance the intensity of the colored stripes via a photoluminescence phenomena. Thus, there is absolutely no disclosure, teaching or suggestion to provide a fluorescing substance selected in the excitation range of either a tumor-specific photosensitizer (as required by Claim 1) or a tissue-autofluorescence (as required by Claim 23).

Gain discloses the provision of a surgical device with a non-toxic photoluminescent substance which includes a "fluorescent" substance. However, as with Iacovelli, there is absolutely no disclosure, teaching or suggestion that the "fluorescent" substance be selected in the excitation range of either a tumor-specific photosensitizer (as required by Claim 1) or a tissue-autofluorescence (as required by Claim 23). This is true because Gain is concerned with a completely different problem

than is the present invention. Gain is simply concerned with improving the visibility of an instrument against the tissue background during normal surgery. As such, there would be absolutely no motivation to modify Gain so as to meet the above-highlighted requirements of all claims.

Moreover, if one were to combine Iacovelli and Gain, one would not reach the invention as claimed. If one combines Iacovelli with Gain, the colored stripes of Iacovelli are provided with a substance showing fluorescence. But nevertheless, this fluorescence serves for enhancing the visibility of the Iacovelli colored stripes to provide a three-dimensional impression to the surgeon. The combination of Iacovelli and Gain does not teach to perform a surgery under the fluorescence modus and to select a compound showing a fluorescence which can be excited with the same light source which excites the fluorescence of the tissue.

Furthermore, none of the tertiary references cited by the Examiner, nor any prior art of which Applicant is aware, discloses, teaches or suggests providing a medical instrument with a fluorescing substance selected in the excitation range of either a tumor-specific photosensitizer (as required by Claim 1) or a tissue-autofluorescence (as required by Claim 23).

For the foregoing reasons, Applicant respectfully submits that all pending claims, namely Claims 1-44, are patentable over the references of record, and earnestly solicits allowance of the same.

Respectfully submitted,



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